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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/392,476	09/09/1999	THERESA C. WHITE	1039.2500-CI	1211

5514 7590 03/26/2004
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NEW YORK, NY 10112

EXAMINER

WAX, ROBERT A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 03/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/392,476

Applicant(s)

WHITE ET AL.

Examiner

Christian L Fronda

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/27/2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9 and 20</u> . | 6) <input type="checkbox"/> Other: _____. |

Art Unit: 1652

DETAILED ACTION

1. Claims 1- 33 are under consideration in this Office Action. New rejections and new grounds of rejection are presented in the instant Office Action.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-21 and 24-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No.6,015,703. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons:

The claims of the instant application directed toward polynucleotides, vector, transformed filamentous fungi, method of making a desired protein using the claimed polynucleotides, vector, and transformed filamentous fungi are genus claims which include the genetically modified microbe, genetic construct, and method of producing beta-glucosidase recited in the patent claims of U.S. Patent No.6,015,703. Thus, allowance of the products and methods as claimed in the instant application would improperly extend the "right to exclude" already granted in U.S. Patent No.6,372,457.

Art Unit: 1652

Claim Rejections - 35 U.S.C. § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-33 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-33, as written, do not sufficiently distinguish over nucleic acids, proteins, cells, or antibodies as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). Claims 1-21 and 24-33 should be amended to indicate the hand of the inventor, e.g., by insertion of "an isolated nucleic acid" or "a purified nucleic acid"; and claims 22 and 23 should be amended by insertion of "isolated protein" or "purified protein". See MPEP 2105.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are genus claims that are directed toward any polynucleotide of any nucleotide sequence from any biological source comprising any regulatory region associated with any xylanase secretion sequence of any nucleotide sequence and any gene of interest including any gene encoding any pharmaceutical or nutraceutical protein, any industrial enzyme, any animal feed, or any food additive. The scope of the claim includes many polynucleotides with widely

Art Unit: 1652

differing structural, chemical, and physical characteristics, and the genus is highly variable because a significant number of structural differences between genus members is permitted. The members of the genus include yet to be discovered polynucleotides encoding yet to be discovered regulatory regions, xylanase secretion sequences, pharmaceutical or nutraceutical proteins, industrial enzymes, animal feeds, and food additives.

The specification describes a vector having the promoter of *cbh1*, *cbh2*, *eg1*, *eg2*, *eg3*, *eg5*, *xln1*, or *xln2*; the coding region of beta-glucosidase, endoglucanase II, beta-mannanase, laccase I, and xylanase; and the secretion signal of *cbh1*, *cbh2*, *eg1*, *eg2*, *eg3*, *eg5*, *xln1*, or *xln2*. The specification describes the use of the said vector to transform bacterial host cells for the purpose of recombinantly producing beta-glucosidase, endoglucanase II, beta-mannanase, laccase I, and xylanase.

However, the specification does not provide the specific nucleotide sequence and corresponding SEQ ID NO: of the said vector having the promoter of *cbh1*, *cbh2*, *eg1*, *eg2*, *eg3*, *eg5*, *xln1*, or *xln2*; the coding region of beta-glucosidase, endoglucanase II, beta-mannanase, laccase I, and xylanase; and the secretion signal of *cbh1*, *cbh2*, *eg1*, *eg2*, *eg3*, *eg5*, *xln1*, or *xln2*.

The specification does not provide a written description of any other polynucleotides encoding yet to be discovered regulatory regions, xylanase secretion sequences, pharmaceutical or nutraceutical proteins, industrial enzymes, animal feeds, and food additives. The specification does not provide a written description of any other protein as encompassed by claims 22 and 23 produced by the method claims 14 and 20 other than beta-glucosidase, endoglucanase II, beta-mannanase, laccase I, and xylanase. The specification does not provide a written description of the nucleotide sequence encoding and amino acid sequence and structure of any "modified thermophilic xylanase" recited in claim 31.

Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Claim Rejections - 35 U.S.C. § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1652

9. Claims 1-30 stand rejected under 35 U.S.C. 102(b) as being anticipated by Suominen et al. (WO93/24621) [the reference has been attached to previous Office Action dated 4/28/2000, Paper No. 8, and is not attached to the instant Office Action].

Applicants' arguments filed 10/27/2000, have been fully considered but they are not persuasive. Applicants' position is that the Suominen et al. reference does not teach the claims as amended, specifically, new claim 33 recites a xylanase II secretion signal for production of desired gene product. Applicants argue that the Suominen et al. only teaches a method for producing a xylanase I protein native to the xylanase I secretion signal and that the instant application teaches a range of different genes not native to the xylanase secretion signal. The Examiner respectfully disagrees for reasons of record as supplemented below.

While Suominen et al. shows in Example 4 (pp. 61-63) a reduction to practice of a plasmid containing a *cbh1* promoter, *xln1* signal sequence for secretion, and coding sequence of the *xln1* gene and a method for making xylanase using the plasmid and a *Trichoderma* strain transformed with said plasmid, the Suominen et al. suggests the idea and concept of using the plasmid to express other proteins and industrial enzymes such as beta-xylosidase, mannanases, and acetyl esterase, where the coding region of the industrial enzyme replaces the coding sequence of the *xln1* gene in the said plasmid. (See p. 14, line 19 to p.27, line 14). Furthermore, Suominen *et al.* teach that the xylanase secretion sequence can be heterologous or homologous with respect to the filamentous fungi (see **Regulatory Regions**, p. 26-27).

Thus, the reference teachings of Suominen et al. anticipate the claimed invention.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private

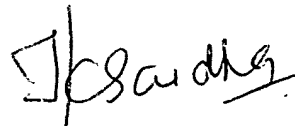
Application/Control Number: 09/392,476

Page 6

Art Unit: 1652

PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF


TEJCHAND SAIDHA
PRIMARY EXAMINER